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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,252	06/27/2001	Peter Styczynski	00216-552001 / H-245 (KAY	1872

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EXAMINER	
WELLS, LAUREN Q	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/893,252	STYCZYNSKI ET AL.	
	Examiner	Art Unit	
	Lauren Q Wells	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,10,11,14,20 and 33-48* is/are rejected.

7)☒ Claim(s) *2-5,7-9,12,13,15-19 and 21-32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/16/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-48 are pending. The Amendment filed 10/16/03, amended claim 1.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/16/03 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, ~~6~~ 7, 33-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Styczynski et al. (6,020,006) in view of Black (WO 99/19466).

The instant invention is directed toward a method of reducing mammalian hair growth which comprises selecting an area of skin on a mammal from which reduced hair growth is desired, and applying to said area of skin, at least once or twice a day over at least two days, a dermatologically acceptable composition comprising an inhibitor of telomerase in an amount effective to reduce hair growth.

Styczynski et al. teach the reduction of hair growth, see title. Specifically taught is a method of reducing mammalian hair growth which comprises selecting an area of skin from which reduced hair growth is desired, and applying to said area of skin a dermatologically acceptable composition comprising an inhibitor of alkaline phosphatase in an amount effective to reduce hair growth, see Col. 6, lines 12-19 of the reference. For the inhibitor comprising 0.1-30% of the composition, see Col. 6, lines 31-32 of the reference. For a reduction of hair growth of at least 30% and 50% when tested in the Golden Syrian hamster assay, see Col. 6, claims 9-10 of the reference. For the inhibitor applied to the skin in an amount of from 10-3000 micrograms per square centimeter of skin, See Col. 6, claim 11 of the reference. For application to a human, to the face, to the leg, to the arm, to the armpit, to the area of skin in conjunction with shaving and to the torso, see Col. 6, claims 13-18 of the reference. For a woman suffering from hirsutism and androgen stimulated hair growth, see Col. 6, claims 19-20. For application once or twice a hair for 2 days (i.e., 48 hours), see Col. 3, line 66-Col. 4, line 12. The reference lacks a telomerase inhibitor.

Black teaches thymidine kinase mutants and fusion proteins having thymidine kinase and guanylate kinase activity. See page 32 for a teaching of nucleoside analogues, such as AZT, as depilatory reagents that destroy hair follicles. The reference specifically states that within other embodiments of the invention, methods are provided for inhibiting the growth of or destroying cells which are not traditionally associated with a disease. . .to destroy hair follicles (as a depilatory reagent).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add AZT, as taught by Black, to the composition of Styczynski et al., a) because

Styczynski et al. teach a method of reducing hair growth further including a second component that also causes a reduction of hair growth (see Col. 6, lines 56-57) and Black teaches AZT as a compound that reduces hair growth; b) because of the expectation of achieving a product with a greater potency in reducing hair growth; c) because it is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose. In re Kerkoven, 205 USPQ 1069 (CCPA 1980).

It is respectfully pointed out that Black teaches AZT as a depilatory reagent. Thus, while an effective amount to reduce hair growth is not explicitly stated, it is respectfully pointed out that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Since a compound and its properties are inseparable, and since AZT is an inhibitor of telomerase, as recited in the instant specification, AZT acts on telomerase and acts on a substrate targeted by telomerase.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Styczynski et al. in view of Black as applied to claims 1, 6, 33-48 above, and further in view of von Borstel et al. (6,702,705).

Styczynski et al. and Black are applied as discussed above. The references lack azacytidine.

Von Borstel et al. teach azacytidine as a nucleoside analogue, see Col. 1, lines 30-54.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute azacytidine, as taught by von Borstel et al., for the AZT of the combined

references a) because Black teaches nucleoside analogues as depilatory agents and azacytidine is a nucleoside analogue, as taught by von Borstel el.; b) because of the expectation of achieving similar depilatory effects. It is respectfully pointed out that it is within the skill of the artisan to substitute one nucleoside analogue for another.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Styczynski et al. in view of Black as applied to claims 1, 6, 33-48 above, and further in view of Stuyver et al. (6,713,251).

Styczynski et al. and Black are applied as discussed above. The references lack dideoxyinosine.

Stuyver et al. teach dideoxyinosine as a nucleoside analogue, see Col. 1, lines 25-63.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute dideoxyinosine, as taught by Stuyver et al., for the AZT of the combined references a) because Black teaches nucleoside analogues as depilatory agents and dideoxyinosine is a nucleoside analogue, as taught by Stuyver et el.; b) because of the expectation of achieving similar depilatory effects. It is respectfully pointed out that it is within the skill of the artisan to substitute one nucleoside analogue for another.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Styczynski et al. in view of Black as applied to claims 1, 6, 33-48 above, and further in view of Redfield et al. (6,479,466)

Styczynski et al. and Black are applied as discussed above. The references lack 3'-doxy-2:3'-didehydrothymidine.

Redfield et al. teach 3'-doxy-2:3'-didehydrothymidine as a nucleoside analogue, see Col. 12, line 59-Col. 13, line 18.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute 3'-doxy-2:3'-didehydrothymidine, as taught by Redfield et al., for the AZT of the combined references a) because Black teaches nucleoside analogues as depilatory agents and 3'-doxy-2:3'-didehydrothymidine is a nucleoside analogue, as taught by Redfield et el.; b) because of the expectation of achieving similar depilatory effects. It is respectfully pointed out that it is within the skill of the artisan to substitute one nucleoside analogue for another.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Styczynski et al. in view of Black as applied to claims 1, ~~6~~ 7, 33-48 above, and further in view of Freeman et al. (6,110,458)

Styczynski et al. and Black are applied as discussed above. The references lack carbovir.

Freeman et al. teach carbovir as a nucleoside analogue, see Col. 5, lines 16-30.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute carbovir, as taught by Freeman et al., for the AZT of the combined references a) because Black teaches nucleoside analogues as depilatory agents and carbovir is a nucleoside analogue, as taught by Freeman et el.; b) because of the expectation of achieving similar depilatory effects. It is respectfully pointed out that it is within the skill of the artisan to substitute one nucleoside analogue for another.

Allowable Subject Matter

Claims 2-6, 7-9, 12-13, 15-19, 21-32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is 571-272-0634. The examiner can normally be reached on M&R (5:30-4).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lqw

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER